

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:)	
Becker, Michael; et al.)	
)	
Title:)	
CONTAINERS AND METHODS FOR)	Examiner: N/a
STORING AND ADMIXING MEDICAL)	
SOLUTIONS)	
)	
Serial No.:)	Art Unit: N/a
(Not yet assigned))	
)	
Filing Date:)	
(Not yet assigned))	

BOX PATENT APPLICATION
 Commissioner for Patents
 Washington, D.C. 20231

PRELIMINARY AMENDMENT

Dear Sir:

Please enter the Preliminary Amendment as follows:

In the Specification:

Please insert the following immediately after the title of the invention and before the section entitled "Background of the Invention," which appears at line 6 of page 1.

-- Cross-Reference to Related Application

This is a continuation application of United States Patent Application No. 09/015,475, which was filed on January 29, 1998, and is a divisional application of United States Patent Application No. 08/712,174, which was filed on September 11, 1996 (abandoned). --

In the Claims:

Also, before calculating the filing fee, please cancel claims 1 through 26 without prejudice and add the following claims:

27. (Added) A container for storing and admixing medical solutions comprising:

a first chamber containing lipids;
a second chamber;
a peelable seal separating the first chamber from the second chamber; and
wherein the lipids have a concentration of a semi-volatile compound of less than 0.011 µg/ml
after the container has been autoclaved and then stands 48 hours at ambient temperature.

28. (Added) The container of claim 27 wherein the semi-volatile compound is selected from the group of 2,6-di-t-butyl-4-methyl-phenol; 2,6-di-t-butyl-4-ethylphenol; and 25-crown-5 ether.

29. (Added) The container of claim 28 wherein the concentration of 2,6-di-t-butyl-4-methyl-phenol is less than 0.050µg/ml.

30. (Added) The container of claim 28 wherein the concentration of 25-crown-5 ether is less than 0.010µg/ml.

31. (Added) The container of claim 27 wherein the container is constructed from a flexible plastic material.

32. (Added) The container of claim 31 wherein the flexible plastic material does not contain polyvinyl chloride.

33. (Added) The container of claim 31 wherein the flexible plastic material is a multilayer film.

34. (Added) The container of claim 33 wherein the multilayer film comprises four layers.

35. (Added) The container of claim 27 wherein the container has been autoclaved at 121 C.

36. (Added) The container of claim 27 wherein the peelable seal is formed by heat sealing.

37. (Added) The container of claim 36 wherein the heat sealing is radio frequency welding.

38. (Added) The container of claim 27 wherein the first chamber and second chamber are defined by a body.

39. (Added) The container of claim 38 wherein the peelable seal is formed by applying a die to the body.

40. (Added) The container of claim 39 wherein the die comprises a seal bar.

41. (Added) The container of claim 40 wherein the seal bar has radiused corners.

42. (Added) The container of claim 40 wherein the seal bar has grooves.

43. (Added) The container of claim 27 wherein the peelable seal separates the first chamber from the second chamber for the length of the container.

44. (Added) A container for storing and admixing medical solutions comprising:
a first chamber containing lipids;
a second chamber;
a peelable seal separating the first chamber from the second chamber; and
wherein the lipids have a concentration of 2,6-di-t-butyl-4-methylphenol of less than 0.050 $\mu\text{g/ml}$ after the container has been autoclaved and then stands for 48 hours at ambient temperature.

45. (Added) The container of claim 44 wherein the container has been autoclaved at 121 C.

46. (Added) A container for storing and admixing medical solutions comprising:
a first chamber containing lipids;
a second chamber;
a peelable seal separating the first chamber from the second chamber; and
wherein the lipids have a concentration of 2,6-di-t-butyl-4-ethylphenol of less than 0.011 $\mu\text{g/ml}$ after the container has been autoclaved and then stands for 48 hours at ambient temperature.

47. (Added) The container of claim 46 wherein the container has been autoclaved at 121 C.

48. (Added) A container for storing and admixing medical solutions comprising:
a first chamber containing lipids;
a second chamber;
a peelable seal separating the first chamber from the second chamber; and
wherein the lipids have a concentration of 25-crown-5 ether of less than 0.010 $\mu\text{g/ml}$ after the container has been autoclaved and then stands for 48 hours at ambient temperature.

49. (Added) The container of claim 48 wherein the container has been autoclaved at 121 C.

50. (Added) A container for storing and admixing medical solutions comprising:
a first chamber containing lipids;
a second chamber;
a peelable seal separating the first chamber from the second chamber; and
wherein the lipids have a concentration of aluminum of less than 0.023 $\mu\text{g/ml}$ after the container has been autoclaved and then stands for 48 hours at ambient temperature.

51. (Added) The container of claim 50 wherein the container has been autoclaved at 121 C.

52. (Added) A container for storing and admixing medical solutions comprising:
a first chamber containing lipids;
a second chamber;
a peelable seal separating the first chamber from the second chamber; and
wherein the lipids have a concentration of oligomeric propylene of less than 5.6 $\mu\text{g/ml}$ after the container has been autoclaved and then stands for 48 hours at ambient temperature.

53. (Added) The container of claim 52 wherein the container has been autoclaved at 121 C.

54. (Added) A container for storing and admixing medical solutions comprising:
a first chamber containing lipids;
a second chamber;
a peelable seal separating the first chamber from the second chamber; and
wherein the lipids have a concentration of oligomeric ethylene vinyl acetate of less than 5.6 µg/ml after the container has been autoclaved and then stands for 48 hours at ambient temperature.

55. (Added) The container of claim 54 wherein the container has been autoclaved at 121 C.

If any other information is needed, please contact the undersigned attorney to expedite the further prosecution of this patent application.

Respectfully Submitted,

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